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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,483

10/04/2006

Mitsuru Hasegawa

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KUBOVCIK & KUBOVCIK

SUITE 1105

1215 SOUTH CLARK STREET

ARLINGTON, VA 22202

EXAMINER

JOHNNIE, JOSEPH G

ART UNIT

PAPER NUMBER

4118

MAIL DATE

DELIVERY MODE

11/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,483	Applicant(s) HASEGAWA, MITSURU	
	Examiner JOSEPH JOHNNIE	Art Unit 4118	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: figure 5, reference numbers 220 and 250. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claim states that where axial length of tip gasket is A, axial length of intermediate gasket is B, axial length of plunger gasket is C, and length from inner wall tip of a nozzle member to an inner wall base end of bypass is D, $A+B+C>D$. However, the specification relevant to this claim refers to Figure 5, in which it is clear that $A+B+C<D$. Moreover, if $A+B+C>D$, it is unclear how the three gaskets would be able to fit inside the barrel. For these reasons, patent examiner will assume that claim 10 intended for $A+B+C<D$.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

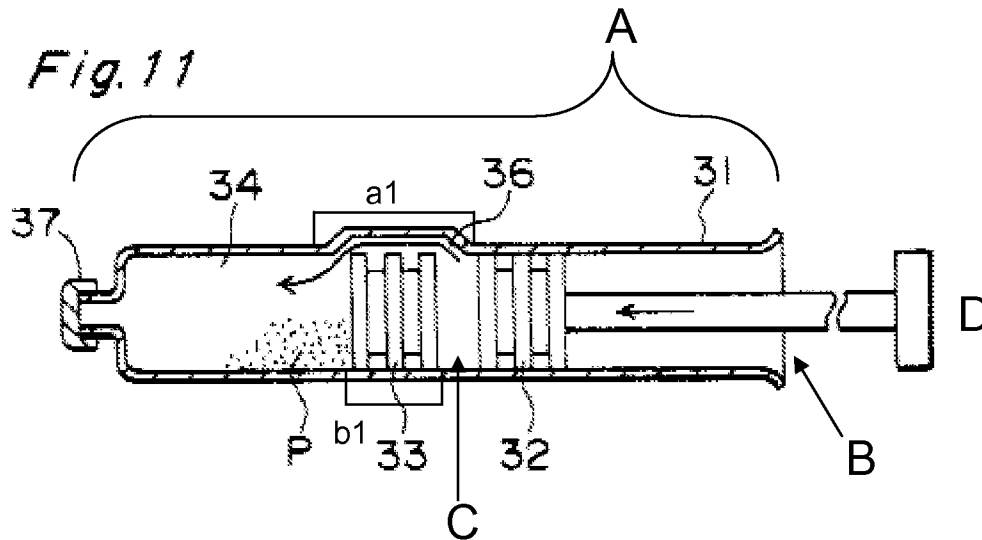
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohtani et al (US Patent No. 5,891,087).

5. In re claim 1, Ohtani discloses a pre-filled syringe comprising: a barrel (element A of figure 11 shown below) having a tip with a nozzle (element 37 of figure 11), an open base end (element B of figure 11 shown below), an intermediate gasket (element 33 of figure 11) liquid-tightly partitioning the inside barrel into a front chamber (element 34 of figure 11) and rear chamber (element C of figure 11 shown below), a sealing plunger gasket located at the base end of the intermediate gasket (element 33 of figure

11), a plunger rod connected to the base, and a bypass protruding outwardly in the radial direction on the tip side of the barrel relative to the intermediate gasket.



6. In re claim 2, Ohtani discloses a syringe where the axial length of the bypass (a1 of figure 11 above) is greater than the axial effective length of the seal (b1 of figure 11 shown above). Refer that $a1 > b1$ in figure 11 shown above.

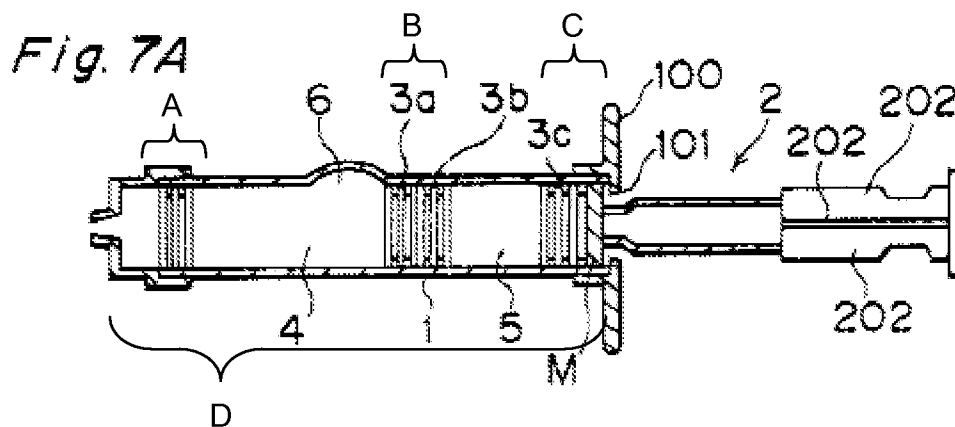
7. In re claim 3, Ohtani discloses a pre-filled syringe wherein the bypass communication passage includes a groove in the circumferential direction (groove 3a in figure 7A).

8. In re claim 4, Ohtani discloses a pre-filled syringe wherein the bypass groove in the circumferential direction is formed in the outer wall of the intermediate gasket 33 (fig. 11).

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9. In re claim 6, Ohtani discloses a connection passage where there is a conduit formed inside the intermediate gasket (elements 102 of figures 7B and 7C).

10. In re claim 9, as best understood, Ohtani discloses a pre-filled syringe wherein if axial length of tip gasket is A (element A of figure 7a below), axial length of intermediate gasket is B (element B of figure 7a below), and axial length of plunger gasket is C (element C of figure 7a below), and length from inner wall tip of nozzle to inner wall base end is D (element D of figure 7a below), $A + B + C < D$.



11. In re claim 10, Ohtani discloses a pre-filled syringe including an intermediate gasket (element B of figure 7a above), a plunger gasket (element C of figure 7a above), and a tip gasket (element A of figure 7a above) with a front chamber (element 4 of figure of figure 7a) formed between the tip gasket and intermediate gasket.

12. Claims 1 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Higashikawa et al (US Patent No. 5,851,200 A).

13. In re claim 1, Higashikawa discloses a pre-filled syringe comprising: a barrel (element 88 of figure 24) having a tip with a nozzle (element A of figure 24 shown below), an open base end (element B of figure 24 shown below), an intermediate gasket

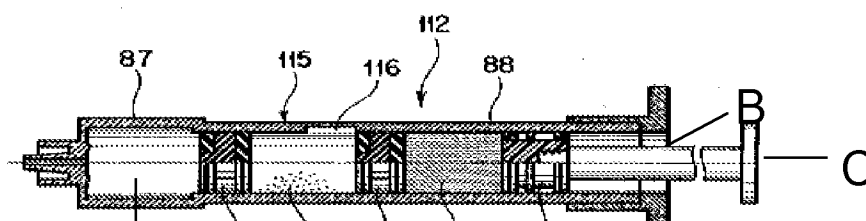
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(element 91 of figure 24) liquid-tightly partitioning the inside barrel into a front chamber (element 113 of figure 24)and rear chamber (element 114 of figure 24), a sealing plunger gasket located at the base end of the intermediate gasket (element 100 of figure 24), a plunger rod connected to the base (element C of figure 24 shown below) and a bypass (element 116 of figure 24).

14. In re claim 10, Higashikawa discloses a prefilled syringe where in there is a tip gasket (element 90 of figure 24), an intermediate gasket (element 91 of figure 24), an open base end (element B), a base end gasket (element 100 of figure 24), a plunger (element C of figure 24 shown below), a bypass near the intermediate gasket (element 116 of figure 24), a front chamber (element A of figure 24), intermediate chamber (element 116 of figure 24), and end chamber (element 114 of figure 24).

15. In re claim 11, Higashikawa discloses a prefilled syringe where in there is an intermediate gasket (element 91 of figure 24), a base end gasket (element 100 of figure 24), a plunger (element C of figure 24 shown below), a bypass near the intermediate gasket (element 116 of figure 24), a front chamber (element 87 of figure 24), intermediate chamber (element 116 of figure 24), an end chamber (element 114 of figure 24), a tip gasket (element 90 of figure 24), and a tip gasket accommodation (element 87 of figure 24), with the tip including a passage through which medicine can pass when the tip gasket is in the tip gasket accommodation part (element 87 of figure 24).

F I G . 24 .



Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohtani et al (US Patent No. 5,891,087) as applied to claim 3 above, and further in view of Hughes (US Patent No. 6554792 B2).

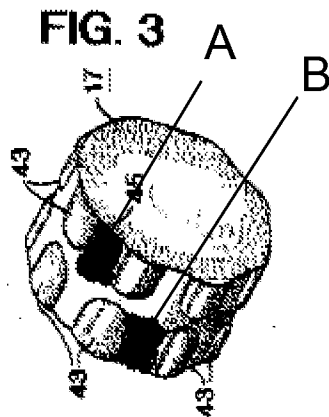
18. In re claim 5, Ohtani discloses all of the claimed invention except for a connection passage on the intermediate gasket which is a spiral shaped groove. Hughes discloses a prefilled syringe including a connection passage which is a spiral groove (element 48 of figures 5 and 6) in the outer wall of the intermediate gasket (element 46 of figure 5). Since the spiral shape is conducive to controlling the flow of a liquid, and the spiral moves around the gasket in a circumferential direction, it would be obvious to modify Ohtani's device to include the grooved spiral connection passage with the bypass in the circumferential direction as taught by Hughes for the purpose of

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providing greater control over the mixing of the substance in the rear compartment with the substance in the front compartment.

19. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohtani et al (US Patent No. 5,891,087) as applied to claim 2 above, and further in view of Michaels (US Patent No. 5,685,846).

20. In re claim 7, Ohtani discloses all of the claimed invention except for a bypass communication passage comprising at least one first groove extending from an intermediate gasket tip side in a base end direction and at least one second groove extending from an intermediate gasket tip side in a tip direction with the tips of the second groove relative to the base end of the first groove. Michaels discloses a bypass communication passage comprising at least one first groove extending from an intermediate gasket tip side in a base end direction (element B of figure 3 below) and at least one second groove extending from an intermediate gasket base end side in a tip direction (element A of figure 3 below), with the tips of the second groove relative to the base end of the first groove. It would be obvious to modify Ohtani's bypass with the grooves, as taught by, Michaels for the purpose of allowing only a desired amount of material flowing from the rear compartment to the front compartment, offering greater control over the mixing of the two substances through the bypass.



21. In re claim 8, Ohtani and Michaels disclose the claimed invention except for establishing the relationship between the length of the bypass in a circumferential direction, a_2 and the length of the distance between the first and second grooves b_2 where $a_2 > b_2$. It would have been an obvious matter of design choice to make the length of the bypass in the circumferential direction greater than the length of the distance between the first and second grooves, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 1, 10 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 11/652001. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims contain essentially the same subject matter of having a barrel, a tip with a nozzle, an open base end, an intermediate gasket, a sealing plunger gasket located at the base end of the intermediate gasket, a plunger rod connected to the base, a bypass protruding outwardly in the radial direction on the tip side of the barrel relative to the intermediate gasket, a tip gasket with a connection pathway between the intermediate and frontal chamber, and frontal, intermediate, and rear chambers.

24. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Walecka (US Patent No. 3,477,431 A).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH JOHNNIE whose telephone number is (571)270-7838. The examiner can normally be reached on Monday-Friday, 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang Thanh can be reached on 571-272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JOSEPH JOHNNIE/
Examiner, Art Unit 4118

/Quang D. Thanh/
Supervisory Patent Examiner,
Art Unit 4118

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